IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN *Plaintiff*	§	
-vs-	§	SA-14-CV-00212-XR
PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC., *Defendant*	§	

ORDER ON MOTION TO DISMISS

On this date, the Court considered Defendant Professional Compounding Centers of America, Inc.'s motion to dismiss (ECF No. 84), the Government's response (ECF No. 91), Defendant's reply (ECF No. 94), and the parties' oral arguments at the hearing held on June 16, 2022. After careful consideration, the Court **DENIES** the motion.

BACKGROUND

Defendant Professional Compounding Centers of America ("PCCA") sells chemical ingredients to compounding pharmacies. Compounding is a practice in which a licensed pharmacist combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. PCCA's pharmacy customers ("members") use these ingredients to prepare and dispense compound medications for patients. The United States of America (the "Government") alleges that, from 2012 to 2015, PCCA and its members reported fraudulently inflated prices for its ingredients for reimbursement purposes and thereby enriched themselves at the expense of the federal TRICARE program, which provides health care coverage for active-duty military personnel, military retirees, and military dependents. *See* ECF No. 66.

The Government alleges that PCCA established and reported fraudulently inflated Average Wholesale Prices ("AWPs")—the pricing metric frequently used to determine TRICARE reimbursement for compound claims—relative to the price at which it actually sold ingredients to member pharmacies. The Government further alleges that PCCA marketed the large "spreads" between the actual selling prices of its ingredients and their respective AWPs to induce its customers to buy its ingredients in violation of the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. §§ 1320a–7b(b). Those customers then submitted claims for compounds containing PCCA ingredients to TRICARE for payment based on PCCA's inflated AWPs, allowing pharmacies to receive "reimbursement" in amounts that were hundreds or thousands of dollars more than what they actually paid to acquire the underlying ingredients in the compound prescription. As explained more fully herein, the Government asserts claims under the False Claims Act ("FCA"), 31 U.S.C. § 3729(a), and federal common law against PCCA for its role in causing TRICARE to pay hundreds of millions of dollars for false and fraudulently inflated claims for compound prescription drugs. ECF No. 66.

I. Factual Allegations

A. TRICARE Reimbursement System

The Government acknowledges that PCCA does not itself submit claims for reimbursement to TRICARE. *Id.* ¶ 52. Instead, as a pharmaceutical supplier, PCCA sells ingredients to compound pharmacies who use those ingredients to prepare and dispense prescription compound drugs to patients. *Id.* PCCA reports AWPs for each of its ingredients to the publishers of drug pricing compendia, which federal health care programs and private insurance companies use to calculate reimbursement rates. *Id.* ¶¶ 52–54.

Separately, PCCA's pharmacy customers submit claims for payment to TRICARE for compound drugs containing PCCA ingredients. *Id.* ¶ 52. These claims are submitted electronically to Express Scripts, Inc. ("ESI"), which contracts with the Government to administer prescription drug coverage for TRICARE beneficiaries. *Id.* ¶ 40. The claims contain, among other things, information about the patient, the prescriber, the pharmacy, the ingredients in the compound drug, pricing information for the ingredients, and the date the prescription was filled. *Id.* ¶ 42.

Pharmacies are required to submit prescription drug claims, including compound claims, to ESI in the current National Council for Prescription Drug Programs ("NCPDP") Telecommunications Standard format. *Id.* ¶ 43. Under the standard for compound pharmacy claims adopted on January 1, 2012 (the "NCPDP D.0" standard), pharmacies are required to submit detailed information about each ingredient within a compound formula, including (1) the ingredient's National Drug Code ("NDC");[1] (2) the quantity of the ingredient; and (3) pricing information for the ingredient. *Id.* ¶ 44. For its part, TRICARE generally reimbursed compound prescription claims based on the lowest of three measurements, in light of the quantity of each ingredient in the compound:

> (1) the sum total of the AWPs (minus a contracted discount) for all ingredients in the compound drug, plus a dispensing fee and level of effort fee;
>
> (2) the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; or
>
> (3) the pharmacy's usual and customary ("U&C") charge for the medication.

Id. ¶ 45.

The Government alleges that TRICARE frequently uses the AWPs for each ingredient in a compound drug to determine the amount pharmacies are reimbursed for the compound

[1] NDCs are unique identifiers, each composed of a three-segment number, assigned to drug products in commercial distribution in the United States. ECF No. 66 at 3 n.2.

prescription claims they submit. *Id.* Moreover, PCCA allegedly assisted its customers in manipulating their U&C prices through its billing software to ensure that pharmacies would be reimbursed according to AWPs rather than an alternative, lower price. *Id.* ¶ 117. The billing software, PK Software, allowed customers to submit claims to third-party payers, including TRICARE, and allegedly featured a setting that enabled pharmacies to automatically report their U&C price for a compound as equal to the AWP-based price. *Id.*

B. Applicable TRICARE Fraud Provisions

Any provider seeking reimbursement from TRICARE must comply with TRICARE's anti-fraud and abuse provisions, 32 C.F.R. § 199.9(a)(4), which are incorporated into the Government's contract with ESI, *see* ECF No. 66 ¶ 168.

To qualify for reimbursement from TRICARE, a drug must be "medically or psychologically necessary [for] the diagnosis and treatment of illness or injury." 32 C.F.R. § 199.4(a)(1)(i); *see also* 32 C.F.R. § 199.4(g)(15). To be medically or psychologically necessary, a drug must, among other things, constitute "appropriate medical care" as defined in TRICARE's regulations. 32 C.F.R. § 199.2. This requires that the care be "furnished economically." *Id.*

TRICARE's regulations further provide that fraud or abuse by a pharmacy or other provider may result in denial of the provider's claims or the exclusion or suspension of the provider from participation in the TRICARE program. *Id.* §§ 199.9(b), (f). Fraudulent practices include arrangements between a supplier and provider that result in claims with unnecessary charges to TRICARE and arrangements designed to overcharge TRICARE, including kickbacks. *Id.* §§ 199.9(c)(12)–(13). Abusive practices include billing TRICARE at rates in excess of those routinely charged to the general public or other third-party payers for similar services or billing substantially in excess of customary or reasonable charges. *Id.* §§ 199.9(b)(2), (7).

ESI's Provider Manuals likewise prohibit pharmacy providers from undermining the U&C or compound price, including by manipulating the U&C price or separating cash business from third-party payer business. *Id.* ¶ 46. ESI Manuals also explicitly prohibit pharmacies from submitting compound claims with inflated AWPs or for amounts in excess of the pharmacy's acquisition costs, "taking into account a reasonable markup." *Id.* ¶ 47.

C. The Anti-Kickback Statute

A claim for reimbursement from a federal health care program for items or services resulting from a violation of the Anti-Kickback Statute "constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Thus, claims submitted to federal health care programs that result from AKS violations are *per se* false or fraudulent within the meaning of the FCA. The AKS makes it illegal for an individual or entity to knowingly and willfully:

> [O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, [or] order . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2). Specific intent to violate the AKS is not required to establish a violation. *Id.*. § 1320a-7b(h).

In 2003, guidance from the Department of Health & Human Services, Office of the Inspector General ("OIG") explicitly warned that AWP manipulation by pharmaceutical manufacturers combined with active marketing of the spread was "strong evidence" of an AKS violation:

> If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal healthcare programs reimburse its customers, the anti-kickback statute is implicated. Unlike *bona fide* discounts, which transfer remuneration from a seller to a buyer, manipulation of the AWP transfers remuneration to a seller's immediate customer from a subsequent purchaser (the federal or state government). Under the anti-kickback statute,

> offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product . . . . **The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product.

68 Fed. Reg. 23731, 23737 (May 5, 2003).

D. PCCA Membership Model

The Government alleges that, in order to purchase products from PCCA, a pharmacy generally had to become a PCCA "member" and abide by the terms of a "membership agreement," which required members to buy 90–100% of their compounding products from PCCA. ECF No. 66 ¶¶ 48, 50. Membership could be terminated at PCCA's discretion if this purchase commitment was not met. *Id.* ¶ 50. PCCA's membership agreements also required an initial, nonrefundable membership fee of between $13,000 and $17,000, with annual renewal fees. *Id.* ¶ 49.

Along with supplying pharmacies with chemical ingredients, PCCA also allegedly provided members with services and information intended to increase their reimbursement rates. Knowing that its members submitted claims to TRICARE for compound drugs containing its ingredients, PCCA actively monitored TRICARE's compound drug reimbursement policies and shared updates on TRICARE coverage with customers. *Id.* ¶ 118. PCCA allegedly taught members how to bill compound claims to get the "widest spread possible," offering access to specialized billing software and a database of over 8,000 suggested formulas for compound drugs. *See id.* ¶¶ 51, 112–17. The Government alleges that PCCA promoted particularly lucrative compound formulas (i.e., specific combinations of ingredients in specific proportions) to further induce sales

of its ingredients—especially those used in pain, wound, and scar creams—even when the formulations were potentially harmful. *See id.* ¶¶ 80–83, 93, 98, 104, 108, 129–34.

PCCA also allegedly rewarded its most loyal customers with all-expenses paid trips to destinations, such as a trip to Cancun, Mexico for "Diamond" customers who made at least $300,000 in annual purchases from PCCA. *See id.* ¶¶ 141–49. PCCA used these trips as a "negotiating tool" and an incentive to purchase more ingredients. *See id.*

E. PCCA's Inflated AWPs and 2012 Increases

The Government alleges that, in March 2012, PCCA sharply increased the AWPs on its ingredients—more than doubling them in some instances. *Id.* ¶ 72 (identifying ten PCCA ingredients and the increase in their AWPs). Specifically, on March 7, PCCA's President, Jim Smith, allegedly directed PCCA's Chief Operating Officer, Fabian Zaccardo, to increase the AWPs on all of PCCA's products. *Id.* ¶ 69. The increased AWPs bore no rational relationship to PCCA's selling prices and generated enormous "spreads" between its customers' acquisition costs and their potential profit from reimbursement. *See id.* ¶¶ 8, 53, 60–61 (identifying ingredients with AWPs ranging from 1,323% to 56,461% of selling prices).

Indeed, PCCA acknowledges that these price increases were adopted in order to increase its market share. PCCA raised AWPs in response to its competitors' decision to inflate AWPs in order to manipulate the reimbursement formula under the NCPDP D.0 after it was adopted in January 2012. *See* ECF No. 84 at 19 (citing ECF No. 66 ¶ 66), ECF No. 66-4 ("[G]iven that [redacted] has become a key competitor for the business of our members who bill insurance, our position will be to follow their list of products and pricing to compete with their offering."); *see also* ECF No. 66 ¶¶ 69, 71 (PCCA president explaining that the "objective" of the AWP increases was to "protect" customers' profit margins and thereby maintain PCCA's market share.) In an

email to senior management two days later, on March 9, 2012, Smith explained that the purpose of PCCA's AWP increases was to maintain PCCA's market share. PCCA also allegedly raised certain already-inflated AWPs even further in direct response to customer requests. *See id.* ¶¶ 84–86 (describing employee who more than doubled the AWP of a certain chemical even after acknowledging that the AWP was "*already* double what it should be" (emphasis added)).

To illustrate the effects of PCCA's AWP increases and marketing efforts, the complaint traces the increase in AWPs for two PCCA ingredients—fluticasone propionate (NDC No. 51927-4330-00) and resveratrol (NDC No. 51927-4367-00)—between 2012 and 2015. *See id.* ¶ 122. Fluticasone propionate is commercially available as prescription topical cream containing 0.05% of the active ingredient and approved by the FDA for the relief of the inflammation and irritation associated with certain skin conditions. *See id.* ¶ 124.

Between 2012 and 2015, PCCA more than doubled its reported AWP for fluticasone propionate, increasing it from $1,500 per gram to $3,757.98 per gram. *Id.* ¶ 126. In 2014, PCCA's AWP for fluticasone propionate was $3,630.90 per gram, even though it typically sold this ingredient to its top customers for between $135.00 and $196.82 per gram. *Id.* To encourage the use of its fluticasone propionate, PCCA allegedly promoted numerous compound drug formulations containing this ingredient, including formulations for skin lightening and scars. *Id.* ¶ 129. Some of the fluticasone topical cream formulas promoted by PCCA contained 1% fluticasone propionate, or 20 times the FDA approved dosage, which PCCA's internal pharmacy consultants warned could be harmful, causing, among other things, delayed immune responses. *Id.* ¶¶ 129–30.

Resveratrol is a "Metabolic Supplement," or a nutritional supplement taken to boost metabolism, which is often sold over the counter for less than $50 for approximately 10 grams. *Id.* ¶¶ 135–36. In 2014, PCCA allegedly sold the ingredient resveratrol to customers for under $2 per

gram but reported an AWP of $818.68 per gram. *Id.* ¶¶ 6, 137. By January 2015, PCCA had further increased the AWP for resveratrol to $847.33 per gram, or more than 400 times PCCA's typical selling price. *Id.* ¶ 138. This created a spread between PCCA's typical selling price and the AWP it reported of more than $840 per gram. *Id.*

PCCA allegedly used its high AWPs and large spreads as a marketing tool to drive sales of its ingredients, knowing that customers would bill TRICARE and other third-party payers based on the inflated AWPs. *Id.* ¶ 74. Because PCCA's selling prices for its ingredients were typically higher than its competitors, PCCA's senior management instructed sales personnel to compete not on selling price, but on AWP reimbursement. *Id.* ¶¶ 75–79. The complaint provides over twenty paragraphs of examples of PCCA's sales representatives marketing its high AWPs and mega-spreads to induce customers to purchase its ingredients. *See id.* ¶¶ 87–111.

The Government alleges that PCCA's active marketing of its AWP inflation caused a dramatic increase in PCCA customers' use of resveratrol and fluticasone propionate in compound prescription claims. *See id.* ¶¶ 132–33, 139. In 2012, PCCA's customers submitted approximately 400 compound prescription claims containing PCCA's fluticasone propionate to TRICARE. *Id.* ¶¶ 133. In the first four months of 2015 alone (from January to May), customers submitted over 16,000 compound prescription claims containing PCCA's fluticasone propionate to TRICARE. *Id.* Between 2012 and 2015, TRICARE paid over $180 million for PCCA's fluticasone propionate. *Id.* ¶ 134.

Similarly, in 2012, only 2 compound prescription claims utilizing PCCA's resveratrol were billed to TRICARE. *Id.* ¶ 139. In the first four months of 2015, PCCA's pharmacy customers submitted over 4,000 compound prescription claims containing PCCA's resveratrol to TRICARE. *Id.* According to the complaint, PCCA's pharmacy customers frequently billed and received

several thousands of dollars in reimbursement from TRICARE for each compound prescription claim containing PCCA's resveratrol based on the ingredient's inflated AWP. *Id.* ¶ 140. One PCCA pharmacy customer allegedly billed and received from TRICARE over $46,000 per claim for several compound claims containing resveratrol and other PCCA ingredients with inflated AWPs. *Id.*

In an exhibit attached to the complaint, the Government provides 325 examples of compound prescription claims submitted to TRICARE for PCCA ingredients, including fluticasone propionate and resveratrol, each of which was reimbursed at thousands of dollars per prescription based on allegedly inflated AWPs. *See* ECF No. 66-22 ("Exhibit 22"). For each claim, Exhibit 22 identifies the date the compound prescription was dispensed, the dispensing pharmacy, the pharmacy state, the payment status, the amount paid, the ingredients contained within the compound prescription claim as submitted, and the corresponding NDC for each ingredient. *See id.*

The complaint alleges that PCCA experienced an explosive growth in sales between 2012 and 2015 as a result of its AWP pricing practices. *Id.* ¶ 158. In 2011, PCCA's annual revenue from sales of its ingredients was approximately $71 million. *Id.* In 2012, PCCA's sales grew to over $100 million. *Id.* In 2013, PCCA's sales grew to $161 million. *Id.* And in 2014, PCCA's sales grew to almost $250 million. *Id.*

PCCA was allegedly concerned that disclosure of its selling prices in comparison to its AWPs could lead payers like TRICARE to discontinue paying for compound claims and knew that at least one payer had already done so. *Id.* ¶ 154. PCCA urged its customers never to disclose its selling prices to auditors because disclosure will "create huge problems for you" and is "a disaster waiting to happen." *Id.* ¶ 156. If an auditor requested an invoice from a PCCA customer, PCCA

advised customers to call PCCA and, in response, PCCA would generate a report for the auditor that would exclude the actual selling prices of PCCA's ingredients from the report. *Id.* ¶ 157.

F. TRICARE's Changes to Reimbursement Process for Compound Claims

The complaint alleges that TRICARE acted to curtail payment even as PCCA lobbied against changes to TRICARE's coverage and payment policies. *See id.* ¶¶ 159–61, 170–71. In October 2014, just months after the relator filed his complaint in this case, *see* ECF No. 1, the Government Accountability Office ("GAO") published a report recommending that TRICARE take additional measures to ensure compliance with applicable regulations and to avoid widespread inflation of AWP. *See* ECF No. 84-1.[2] One month later, the DOD Pharmacy and Therapeutics ("P&T") Committee unanimously recommended a prior authorization process for compound claims. ECF No. 66 ¶ 160. Following input from TRICARE's Beneficiary Advisory Panel, TRICARE implemented enhanced electronic screening and prior authorization for compound claims, effective May 2015. *Id.* ¶ 161.

As TRICARE worked to change its reimbursement policies, PCCA recognized that TRICARE's continued coverage of its compound drug ingredients and bases was critical to its profits. *Id.* ¶ 159. In March 2014, a lobbyist for PCCA wrote to PCCA's President about "the latest on the TRICARE compounded pharmacy situation," stating that "there will be a further delay in their (TRICARE/DOD) decision," and that "another delay equals another victory for PCCA and ALL of your member pharmacies." ECF No. 66-31.

[2] While the GAO report is not referenced in the complaint, PCCA asks the Court to take judicial notice of its contents as a matter of public record, *see* ECF No. 84 at 20–21, and the Government does not appear to oppose the request. The Court concludes that judicial notice of the report is warranted here. *See Norris v. Hearst Tr.*, 500 F.3d 454, 461 n.9 (5th Cir. 2007) ("[I]t is clearly proper in deciding a 12(b)(6) motion to take judicial notice of matters of public record."). The Court will also take judicial notice of the GAO report issues in July 2002, entitled "VA and DOD Health Care, Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges," GAO-02-969T. *See* ECF No. 84-2 (the "2002 GAO Report").

According to the complaint, once TRICARE implemented its prior authorization process, the number of fraudulently inflated compound claims to TRICARE declined sharply—along with PCCA's sales. *See id.* PCCA's annual revenue allegedly fell from over $244 million in 2014 to under $90 million in 2015, with the sharpest decline in "Diamond" level customers. *Id.* ¶ 163. In an email dated June 2015 discussing the previous month's sales, PCCA's President acknowledged that "Tricare changes in reimbursement took a huge toll on our members' purchases." *Id.* ¶ 162. Figures in the same email chain revealed that monthly sales declined from over $24.5 million in May 2014 to $14.9 million in May 2015. *Id.*

Before the changes to TRICARE reimbursement were implemented, the Government alleges that it paid hundreds of millions of dollars in excess reimbursement for tens of thousands of artificially inflated compound prescription claims containing PCCA ingredients as a result of PCCA's fraudulent course of conduct. *Id.*

II. Procedural History

In March 2014, the relator, Peter Hueseman—a pharmacist who formerly worked at a pharmacy that purchased from PCCA—filed his complaint in this matter under the FCA's qui tam provisions, alleging that PCCA's fraudulent AWP scheme violated the FCA and the AKS. *See* ECF No. 1. After investigating the matter, the Government filed its complaint in partial intervention in November 2021, asserting FCA claims against PCCA for causing the submission of false claims to TRICARE and for reporting false AWPs to the pricing compendia on which TRICARE reimbursement is based. ECF No. 66 at 43–44.[3] The Government further asserts federal common law claims for payment by mistake, unjust enrichment, and fraud. *Id.* at 44–46.

[3] Page numbers in citations to the record refer to PDF page numbers as the document was filed on CM/ECF, which are not necessarily the same as the page numbers in the underlying documents.

Now pending before the Court is PCCA's motion to dismiss the complaint in its entirety under Rule 12(b)(6) of the Federal Rules of Civil Procedure. ECF No. 84. The Government opposes dismissal. ECF No. 91. The Court heard oral arguments in June 2022, and took the motion under advisement.

LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows a party to move for the dismissal of a complaint for "failure to state a claim upon which relief can be granted." To survive a motion to dismiss, "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

"Claims alleging fraud and fraudulent inducement are subject to the requirements of Rule 9(b) of the Federal Rules of Civil Procedure." *Schnurr v. Preston*, No. 5:17–CV–512–DAE, 2018 WL 8584292, at *3 (W.D. Tex. May 29, 2018). Rule 9(b) states that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). "[A]rticulating the elements of fraud with particularity requires a plaintiff to specify the statements contended to be fraudulent, identify the speaker, state when and where the statements were made, and explain why the statements were fraudulent." *Williams v. VMX Techs., Inc.*, 112 F.3d 175, 177 (5th Cir. 1997). "Directly put, the who, what, when, and where must be laid out." *Id.* at 178. "Facts and circumstances constituting charged fraud must be specifically demonstrated and cannot be presumed from vague allegations." *Howard v. Sun Oil Co.*, 404 F.2d 596, 601 (5th Cir. 1968). "Anything less fails to provide defendants with adequate notice of the nature and

grounds of the claim." *Hart v. Bayer Corp.*, 199 F.3d 239, 247 n.6 (5th Cir. 2000). "Although the language of Rule 9(b) confines its requirements to claims of . . . fraud, the requirements of the rule apply to all cases where the gravamen of the claim is fraud even though the theory supporting the claim is not technically termed fraud." *Frith v. Guardian Life Ins. Co. of Am.*, 9 F. Supp. 2d 734, 742 (S.D. Tex. Mar. 31, 1998).

In considering a motion to dismiss under Rule 12(b)(6), all factual allegations from the complaint should be taken as true, and the facts are to be construed in the light most favorable to the nonmoving party. *Fernandez-Montes v. Allied Pilots Assoc.*, 987 F.2d 278, 284 (5th Cir. 1993). Still, a complaint must contain "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. "'[N]aked assertions' devoid of 'further factual enhancement,'" and "threadbare recitals of the elements of a cause of action, supported by mere conclusory statements," are not entitled to the presumption of truth. *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 557); *see also R2 Invs. LDC v. Phillips*, 401 F.3d 638, 642 (5th Cir. 2005) (stating that the Court should neither "strain to find inferences favorable to plaintiffs" nor accept "conclusory allegations, unwarranted deductions, or legal conclusions.").

DISCUSSION

I. Violations of the False Claims Act, 31 U.S.C. § 3729(A)(1)(A)–(B)

To succeed on a claim for violation of the FCA, the Government or relator must prove:

1) there was a false statement or fraudulent course of conduct;

2) made or carried out with the requisite scienter;

3) that was material; and

4) that caused the government to pay out money or to forfeit moneys due (i.e., that involved a claim).

See United States ex rel. Longhi v. Lithium Power Techs., Inc., 575 F.3d 458, 467 (5th Cir. 2009) (citing 31 U.S.C. § 3729(a)). Individuals or entities who violate the FCA are liable for treble damages as well as civil penalties of not less than $5,500 and not more than $11,000 for each false claim. 31 U.S.C. § 3729(a)(1); 64 Fed. Reg. 47099, 47103–04 (Aug. 30, 1999) (adjusting civil penalties amount pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990).

A. False Statement or Fraudulent Course of Conduct

The False Claims Act prohibits false and fraudulent claims for reimbursement to the federal government. An entity violates the FCA when it:

> 1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;[or]
>
> 2) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim[.]

31 U.S.C. §§ 3729(a)(1)(A)–(B). The Government alleges that PCCA knowingly (1) caused its members to submit claims that falsely implied certification with the AKS and TRICARE regulations, and (2) submitted false AWPs to the third-party pricing compendia that were material to its members reimbursement by TRICARE. ECF No. 66 at 43–44.

The FCA attaches liability "not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *Longhi*, 575 F.3d at 467 (citing *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 785 (4th Cir. 1999)). For purposes of the FCA, "claim" means:

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that
>
> (i) is presented to an officer, employee, or agent of the United States; or

> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—
>
> (I) provides or has provided any portion of the money or property requested or demanded; or
>
> (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

PCCA insists that it cannot be liable under the FCA because it has never itself been a "claimant" to the Government and does not even have a billing number that would allow it to bill TRICARE. ECF No. 84 at 29. In fact, PCCA observes, it submitted the allegedly false AWPs not to TRICARE or the Government more broadly, but to third-party publishers of drug-pricing data, *Id.* at 24. The Government does not dispute this characterization of PCCA's conduct, but its impact on PCCA's liability under the FCA. ECF No. 91 at 44–45.

That PCCA did not itself submit claims to TRICARE is irrelevant because "the FCA reaches anyone who 'causes' the submission of a false claim or who makes or causes to be made or used a false statement material to a false claim." *Id.* (citing 31 U.S.C. §§ 3729(a)(1)(A)–(B)). Thus, "a person need not be the one who actually submitted the claim forms in order to be liable." *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 378 (5th Cir. 2004) (quotations omitted); *see also Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) (FCA was designed to "reach any person who knowingly assisted in causing the government to pay claims which were grounded in fraud").

PCCA further asserts that the Government has failed to "sufficiently tie PCCA's alleged misconduct to any actual claims." ECF No. 84 at 15. The Court disagrees. As discussed herein, the complaint satisfies the particularity requirements of Rule 9(b) by alleging "particular details of

a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *See United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009); ECF No. 66-22. As the Fifth Circuit has explained, "a plaintiff does not necessarily need the exact dollar amounts, billing numbers, or dates to prove to a preponderance that fraudulent bills were actually submitted." *Grubbs*, 565 F.3d at 190. "To require these details at pleading is one small step shy of requiring production of actual documentation with the complaint, a level of proof not demanded to win at trial and significantly more than any federal pleading rule contemplates." *Id.*

1. Presentment Claim – § 3729(a)(1)(A)

The Government alleges that PCCA's fraudulent conduct caused its customers to submit TRICARE claims that impliedly and falsely certified compliance with TRICARE regulations, ESI's provider agreements, and the AKS. ECF No. 66 at 43.

"False or fraudulent claims" are not limited to claims containing express falsehoods. Claims may also be false where they implicitly certify that they comply with a material statutory, regulatory, or contractual requirement. Liability under an "implied false certification theory" attaches "at least" where a claim "makes specific representations about the goods or services provided" and "failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Universal Health Servs., Inc. v. United States ex rel. Escobar ("Escobar")*, 579 U.S. 176, 190 (2016). Even where there is no expressly certified compliance, an implied certification of compliance through the mere submission of a claim for payment can be sufficient for FCA liability, at least where falsity is premised on an AKS violation. *United States ex rel. Colquitt v. Abbott Labs.*, 858 F.3d 365, 372 n.2 (5th Cir. 2017) (citing *Escobar*, 579 U.S. at 190) (concluding that absence of certification with

AKS did not preclude liability under the FCA); *United States ex rel. Jamison v. Career Opportunities, Inc.*, No. 3:16-CV-3248-S, 2020 WL 520590, at *2, 4–6 (N.D. Tex. Jan. 31, 2020) (where defendant allegedly recorded false data used on reimbursement forms submitted to DOL, allegations sufficiently stated presentment of false claims and false statements material to false claims, even though claims did not include any "certification" that the information was "true and correct").

The AKS makes it illegal for an individual or entity to knowingly and willfully:

> [O]ffer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase, lease, [or] order . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. § 1320a-7b(b)(2). The AKS expressly provides that "a claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the FCA]." *Id.* § 1320a-7b(g). Under this provision, claims submitted to federal health care programs that result from AKS violations are per se false or fraudulent within the meaning of the FCA. *Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019) (collecting cases to support its holding that, given the plain language of § 1320a-7b(g), courts need not inquire whether the entity submitting the claim had certified its compliance with the AKS). AKS violations are also "inherently material" under the FCA "to the government's decision to pay claims presented." *United States v. Marlin Med. Sols., LLC,* No. SA-21-CV-00160-OLG, 2022 WL 190308, at *8 (W.D. Tex. Jan. 12, 2022). "[A] person need not have actual knowledge of [the AKS] or specific intent to commit a violation of [the AKS]." 42 U.S.C. § 1320a–7b(h). Rather, it is sufficient for the Government to plead "that the defendant willfully committed an act that violated the [AKS]*." United States v. St. Junius*, 739 F.3d 193, 210 (5th Cir. 2013).

The Government pleads a violation of the AKS where it alleges that the defendant (1) knowingly and willfully offered remuneration to any person; (2) to induce such person; (3) to purchase or arrange for the purchase of any item; (4) for which payment may be made in whole or in part under a federal health care program. *See United States v. Medoc Health Servs. LLC*, 470 F. Supp. 3d 638, 648 (N.D. Tex. 2020).

The complaint alleges that PCCA knowingly and willfully offered remuneration to its customers—in the form of egregiously inflated AWPs, corresponding profit spreads, and other benefits such as all-expense paid vacations—to induce customers to purchase PCCA ingredients billed to TRICARE. ECF No. 66 ¶¶ 52–111, 141–49. This is not a surprising theory of liability. Indeed, in 2003, the DHHS OIG warned that AWP manipulation combined with active marketing of the spread was "strong evidence" of an AKS violation. 68 Fed. Reg. at 23737. Such improper marketing includes "sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product." *Id.* The OIG Guidance clearly states that "it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the 'spread; to induce customers to purchase its product[.]" *Id.*

PCCA objects that the Government failed to tie that remuneration to specific claims for payment.[4] ECF No. 84 at 54. The Government does not need to tie specific offers of remuneration

[4] In supplemental briefing, PCCA argues that the Eighth Circuit's recent ruling in *United States ex rel. Cairns v. D.S. Med. LLC* requires dismissal of the complaint. *See* ECF No. 101 (citing 42 F.4th 828, 831 (8th Cir. 2022)). In *Cairns*, the Eighth Circuit interpreted the "resulting from" language in 42 U.S.C §1320a-7b(g) of the AKS to require but-for causation "when a plaintiff seeks to establish falsity or fraud through" that provision. 42 F.4th at 836 (reversing and remanding for new trial where the district court failed to instruct the jury on but-for causation because the "government's sole theory at trial hinged" on Section 1320a-7b(g)). This Court is neither bound nor persuaded by the Eighth Circuit's reasoning, which has been rejected by numerous courts. *See, e.g.*, *United States ex rel. Greenfield v. Medco Health Sols., Inc.*, 880 F.3d 89 (3d Cir. 2018); *United States ex rel. Fitzer v. Allergan, Inc.*, No. 1:17-cv-00668-SAG, 2022 WL 3599139, at *10 (D. Md. Aug. 23, 2022) ("This Court declines to adopt the but-for cause standard endorsed by *Cairns*[.]"); *United States ex rel. Everest Principals, LLC v. Abbott Labs., Inc.*, No. 3:20-cv-286-

to particular claims to plead FCA claims premised on underlying AKS violations. *See Marlin Med.*, 2022 WL 190308, at *4 (government need only plead particular details of a scheme paired with reliable indicia leading to a strong inference that claims were actually submitted). Nonetheless, the Government has identified 325 claims containing PCCA's ingredients that were allegedly submitted to TRICARE by PCCA's customers and reimbursed based on fraudulently inflated AWPs pursuant to an unlawful kickback scheme. *See* ECF No. 66-22. Because this is sufficient to establish a plausible allegation of falsity under the FCA, the Court need not address the customers' implied certification with TRICARE regulations and their agreements with ESI.

2. False Records Claim - § 3729(a)(1)(B)

To allege falsity under § 3729(a)(1)(B), the Government must allege "the recording of a false record" that is material to a claim for payment. *Grubbs*, 565 F.3d at 193. The false statement need not be made to the Government, so long as the defendant knew it would be material to a payment by the Government. *See Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671–72 (2008); *United States ex rel. Int'l Bhd. of Elec. Workers Loc. Union*, *No. 98 v. Farfield Co.*, 5 F.4th 315, 324 (3d Cir. 2021). Here, the complaint alleges that PCCA reported fraudulently inflated AWPs, knowing that they would be used to determine TRICARE reimbursement amounts. ECF No. 66 ¶¶ 53–64, 152–63.

W(AGS), 2022 WL 3567063, at *8 (S.D. Cal. Aug. 18, 2022) (acknowledging the split of authority, but requiring only a "'link' at this stage of the proceedings").

Regardless of the wisdom of *Cairns*, the question of whether to endorse its causation standard is not properly before the Court at this stage of the proceedings. First, PCCA did not raise this argument in its motion to dismiss, and the Court typically does not consider arguments raised for the first time in a reply brief or supplemental briefing. *See Espinoza v. Pompeo*, No. SA-19-CV-01363-XR, 2020 WL 1941300, at *5 (W.D. Tex. Apr. 22, 2020). More importantly, *Cairns* is inapplicable here because the Government does not rely "exclusively" on the AKS to demonstrate falsity. *See Cairns*, 42 F.4th at 836 ("We do not suggest that every case arising under the False Claims Act requires a showing of but-for causation."). Rather, as discussed herein, the Government has asserted alternative theories of falsity under the FCA and other claims for recovery under federal common law.

PCCA repeatedly argues that its AWPs cannot be "objectively false"—no matter how divorced from its actual prices—because there is no statutory or regulatory "definition" of AWP. ECF No. 84 at 11–12, 14–15, 17–19, 23–24, 36, 48–50, 52–53. The Fifth Circuit recently rejected an "objective falsity" standard in the context of a criminal health care fraud case, however, explaining that "health care providers cannot immunize themselves from prosecution by cloaking fraud with a doctor's note" and "[c]ategorical evidentiary requirements are at odds with a jury's ability to consider a broad array of direct and circumstantial evidence." *See United States v. Mesquias*, 29 F.4th 276, 282–83 (5th Cir. 2022). Similarly, an objective falsity requirement is "inconsistent with the [FCA.]" *United States ex rel. Druding v. Care Alternatives*, 952 F.3d 89, 95 (3d Cir. 2020); *accord United States ex rel. Winter v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1119 (9th Cir. 2020); *Escobar*, 579 U.S. at 192 (cautioning against "adopting a circumscribed view of what it means for a claim to be false or fraudulent." (quotations omitted)).

Indeed, courts have routinely recognized that when AWPs are fictitious numbers bearing no rational relationship to any actual price, they are false or fraudulent. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 178–84 (1st Cir. 2009); *In re Lupron Mktg. & Sales Pracs. Litig.*, 295 F. Supp. 2d 148, 167 (D. Mass. 2003). The absence of a specific definition for AWP does not grant companies unfettered discretion to use AWPs as an instrument of fraud. *See, e.g.*, *United States ex rel. Rahimi v. Zydus Pharm., Inc.*, No. 15-6536-BRM-DEA, 2017 WL 1503986, at *11 (D.N.J. Apr. 26, 2017) ("[C]ourts have consistently rejected the notion that AWPs can be defined as whatever price drug manufacturers chose to publish through pricing compendia."); *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 145 (D. Mass. 2008) (finding wholesale prices "that were far, far higher than the price that most (if not all) wholesalers actually paid," sometimes over a hundred times more than the amount actually paid, sufficient to establish

falsity); *see id.* at 144 (rejecting drug manufacturers' proposed definition of AWP as an undiscounted "list price" because it would give them "a virtual blank check" and "[t]he suggestion that the Commonwealth 'intended to give the pharmaceutical industry free reign over drug pricing' is absurd").

Contrary to PCCA's assertions, the complaint's emphasis on the AWP increases between 2012 and 2015 does not imply that the Government condones the pre-2012 AWPs. *See* ECF No. 84 at 17 (arguing that the complaint fails to explain how "an AWP that is 3000% of an active pharmaceutical ingredient's acquisition cost [after March 2012] is 'fraudulently inflated' while one that [was] 1500% of that acquisition cost [before March 2012] is not fraudulent"). To the contrary, the complaint notes that PCCA's AWPs were "already inflated" prior to the increases in March 2012, ECF No. 66 ¶ 138. By addressing the mechanisms and justifications for the price increases in 2012 and beyond, however, the allegations suggest that PCCA knew that its AWP increases were excessive and untethered to selling price. The Government merely limited the claims in this action in time, which already amount to hundreds of millions of dollars in inflated TRICARE reimbursements.[5] *Id.* ¶¶ 1, 16, 173, 179.

B. Scienter

The FCA applies to those who "knowingly assist[] in causing the government to pay claims which were grounded in fraud, without regard to whether that person had direct contractual relations with the government." *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975). A person acts "knowingly" with respect to information if the person "has actual knowledge of the information," "acts in deliberate ignorance of the truth or falsity of the information," or "acts in

[5] PCCA's contention that it is not "obligated" to report AWPs is similarly unavailing. ECF No. 84 at 19. PCCA chose to report AWPs, knowing that they would be used to determine TRICARE reimbursement to its customers. "[I]f the defendant does speak, he must disclose enough to prevent his words from being misleading." *Escobar*, 579 U.S. at 188 n.3 (quotations omitted).

reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b). It "require[s] no proof of specific intent to defraud." *Id.* § 3729(b)(1)(B). "Knowledge need not be pled with particularity under Rule 9(b); it need only be pled plausibly pursuant to Rule 8." *United States v. Bollinger Shipyards, Inc.*, 775 F.3d 255, 260 (5th Cir. 2014).

The Government alleges that PCCA knew (1) that the AWPs it submitted to the third-party pricing compendia were false, *see* ECF No. 66 ¶¶ 65–72, 85; (2) that its customers submitted claims for compounds using its chemicals to TRICARE seeking reimbursement based on fraudulent AWPs, *see id.* ¶¶ 5, 55, 56, 59, 64, 118, 159; (3) that its inflated AWPs would drive customers to purchase and submit claims for ingredients solely because of their reimbursement potential, *see id.* ¶¶ 5, 64, 65, 74; and (4) that the AWPs were material to payment decisions by insurers like TRICARE, *see id.* ¶¶ 5, 152–59. Nonetheless, PCCA contends that the complaint fails to adequately allege the knowledge requirement because it fails to define AWP and because it does not satisfy the scienter standard set out in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007). *See* ECF No. 84 at 42–55. The Court addresses each argument in turn.

PCCA first argues that, because the complaint fails to explicitly define AWP, the Government cannot adequately plead that PCCA knew—or even could have known—that claims submitted by its customers based on AWPs were false. *Id.* The Fifth Circuit explicitly rejected this theory of scienter in *Bollinger Shipyards*. *See* 775 F.3d at 260. There, the district court concluded that the defendant had not acted knowingly under the FCA by reporting certain inaccurate figures to the Coast Guard because "the United States failed to allege that [the defendant] knew the correct . . . figure and therefore concealed the true calculation." 775 F.3d at 261. The Fifth Circuit reversed the district court, explaining that "[t]he FCA does not require the United States to show that [defendant] knew the *correct* figure." *Id.* (emphasis in original). According to the Fifth Circuit,

"[t]he FCA is satisfied if the plaintiff alleges the defendant either knew the [reported] figure was false or acted with reckless disregard of its truth or falsity." *Id*. The district court also erred by drawing inferences against the Government and in favor of the defendant and by failing to consider "circumstantial evidence and general allegations of [the defendant's] knowledge and intent." *Id.*

In construing the FCA's scienter standard, every Circuit to consider the question has adopted the Supreme Court's decision in *Safeco*.[6] *Safeco* defined another common law term, "willfully"—as used in the Fair Credit Reporting Act—which the Court interpreted as encompassing the same common law scienter terms used in the FCA ("knowingly" or "reckless disregard"). While reiterating that "knowingly" and "reckless disregard" remain distinct terms, the Supreme Court announced a standard inquiry for reckless disregard. *Safeco*, 551 U.S. at 60, 70 n.20. The Court applied the common law usage of "reckless" and held that "a company subject to FCRA does not act in reckless disregard of it unless the action is not only a violation under a reasonable reading of the statute's terms, but shows that the company ran a risk of violating the law substantially greater than the risk associated with a reading that was merely careless." *Id*. at 69. The Court later cabined this holding in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, clarifying that a defendant could not avoid enhanced damages under the Patent Act by asserting an objectively reasonable defense that it did not hold at the time. 579 U.S. 93, 106 (2016).

Even assuming that Fifth Circuit would join other Circuits in extending the *Safeco* standard to FCA cases, the Government argues that *Safeco* would not excuse liability for a post hoc

[6] *See United States v. SuperValu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021), *cert. granted*, 143 S. Ct. 644 (2023); *United States ex rel. Sheldon v. Allergan Sales*, LLC, 24 F.4th 340, 348 (4th Cir. 2022); *United States ex rel. Streck v. Allergan*, 746. App'x 101, 106 (3d Cir. 2018); *United States ex rel. McGrath v. Microsemi Corp.*, 690 F. App'x 551, 552 (9th Cir. 2017); *United* States *ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879–80 (8th Cir. 2016); *United States ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 284 (D.C. Cir. 2015).

interpretation of regulations that PCCA never *actually* took.[7] *See* ECF No. 91 at 61–62. Citing the Seventh Circuit's opinion in *United States ex rel. Schutte v. SuperValu*, PCCA insists that "[a] defendant's subjective intent is irrelevant" under *Safeco*, ECF No. 84 at 45 (citing 9 F.4th at 464), which "covers all three of the scienter standards listed in § 3729," ECF No. 94 at 10 (citing 9 F.4th at 468). The parties' disagreement on this point is unsurprising—it is at the very heart of the question the Supreme Court will face when it considers *SuperValu* later this term: "Whether and when a defendant's contemporaneous subjective understanding or beliefs about the lawfulness of its conduct are relevant to whether it 'knowingly' violated the False Claims Act." *See* Petition for a Writ of Certiorari at 3, *SuperValu*, 143 S. Ct. 644 (No. 21-1326) (hereinafter, "*SuperValu* Petition").[8] *Bollinger Shipyards* suggests that, for its part, the Fifth Circuit would disagree with *SuperValu*'s holding that intent is irrelevant to scienter. *See* 775 F.3d at 261 (explaining that the district court should have considered the "circumstantial evidence and general allegations of [the

[7] PCCA states that, under *Safeco*, it "could have" held "a completely, objectively reasonable interpretation" that its products were not subject to TRICARE reimbursement because they have not been cleared/approved by the FDA. ECF No. 84 at 46. "As such, it could not have known that any action it took would have resulted in any claim being submitted to TRICARE, because its products were not covered by federal payors." *Id.* As the Government points out, this interpretation is objectively unreasonable because neither the FCA nor the AKS is limited to fraudulent or kickback schemes for items that are "covered" or "reimbursable." ECF No. 91 at 63.

Moreover, to the extent that PCCA knowingly caused its customers to submit claims that were ineligible for reimbursement, it is not clear to the Court how PCCA's interpretation of TRICARE regulations would excuse it from liability under the FCA. After all, a claim submitted to the government for items that are not covered or eligible for payment is itself a false claim under the FCA. *Peterson v. Weinberger*, 508 F.2d 45, 52 (5th Cir. 1975) ("[T]he services billed were plainly not 'covered' and the Government thus paid on the basis of the false claims presented."); *United States ex rel. McNutt v. Haleyville Med. Supplies, Inc.*, 423 F.3d 1256, 1260 (11th Cir. 2005) (government adequately alleged FCA and AKS violations where defendant submitted claims "knowing that they were ineligible for the payments demanded in those claims"). Finally, the Court agrees with the Government that PCCA's argument that TRICARE is responsible for the unauthorized reimbursements constitutes an attempt to estop the Government from enforcing the law based on the supposed actions of its agents. *See Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 53, 65–66 (1984) (holding that a Medicare provider could not stop the government from seeking a return of Medicare funds even though the provider relied on advice of the government's agent).

[8] https://www.supremecourt.gov/DocketPDF/21/21-1326/220086/20220401160219413_Schutte%20Petition%20and%20Appendix.pdf.

defendant's] knowledge and *intent*" in determining whether the government had adequately pled scienter) (emphasis added).

The Court observes from the outset that, as a matter of sheer semantics, it is bizarre to suggest that subjective intent is irrelevant to *any* evaluation of scienter. *See* Scienter, Black's Law Dictionary (11th ed. 2019) ("A *mental state* consisting in an *intent* to deceive, manipulate, or defraud." (emphasis added)); *see also Unicolors, Inc. v. H&M Hennes & Mauritz, L.P.*, 142 S. Ct. 941, 946–47 (2022) (ordinary meaning of "knowledge" is "actual subjective awareness of both facts and the law"). It is stranger still to conclude that the most reliable way to discern scienter is to disregard all evidence of a defendant's subjective intent and simply *imagine*—in the abstract—a lawful explanation for his conduct. As the *SuperValu* petitioners point out:

> [U]nder the Seventh Circuit's rule, even if a defendant *believes* it is presenting false claims, *wants* to present false claims, and *in fact* presents false claims, the defendant cannot be found to have "knowingly" presented false claims if the defendant's lawyers can later convince a court in litigation that the defendant's conduct fell within a reasonable interpretation of the law.

SuperValu Petition at 14–15 (emphasis in original). This theory is at direct odds with the longstanding principle that "[m]en must turn square corners when they deal with the Government." *Rock Island Ark. & La. R.R. v. United States*, 254 U.S. 141, 143 (1920), especially "when a private party seeks to spend the Government's money." *Heckler v. Cmty. Health Servs. of Crawford Cnty., Inc.*, 467 U.S. 51, 63 (1984).

In this Court's view, *SuperValu*'s interpretation of the scienter requirement is also inconsistent with the Supreme Court's discussion of scienter and materiality in *Escobar*, 579 U.S. at 191. First, *Escobar* contemplates FCA liability even for *implicit* conditions of payment:

> A defendant can have "actual knowledge" that a condition is material without the Government expressly calling it a condition of payment. If the Government failed to specify that guns it orders must actually shoot, but the defendant knows that the Government routinely rescinds contracts if the guns do not shoot, the defendant has

> "actual knowledge." Likewise, because a reasonable person would realize the imperative of a functioning firearm, a defendant's failure to appreciate the materiality of that condition would amount to "deliberate ignorance" or "reckless disregard" of the "truth or falsity of the information" even if the Government did not spell this out.

Id. It also contemplates liability for violations that most people would consider immaterial, at least where the defendant is aware that the Government (unreasonably) considers the violation material:

> Under any understanding of the concept, materiality "look[s] to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." In tort law, for instance, a "matter is material" in only two circumstances: (1) "[if] a reasonable man would attach importance to [it] in determining his choice of action in the transaction"; or (2) if the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter "in determining his choice of action," even though a reasonable person would not.

See id. at 193 (citations omitted). *Escobar* confirms that FCA liability may attach based on a defendant's actual, subjective understanding of the Government's interpretation of the law, even when the Government's interpretation is unreasonable. Thus, *Escobar* not only undermines *SuperValu*'s conclusion that subjective intent is "irrelevant," but also its assumption that conditions of payment must be explicit in order to be controlling. *See id.* at 191 ("Nothing in the text of the [FCA] . . . . limit[s] such claims to misrepresentations about express conditions of payment. Nor does the common-law meaning of fraud tether liability to violating an express condition of payment.").

Finally, even under the Seventh Circuit's view of the scienter requirement, PCCA's arguments are wholly inappropriate at this stage of the proceedings. Both *Safeco* and *SuperValu* reviewed district court orders on motions for summary judgment. By arguing for dismissal here, PCCA suggests that an FCA claimant must identify every conceivable incorrect interpretation of the regulation(s) at issue and explain how each interpretation was either unreasonable or foreclosed by authoritative guidance. The Court declines to impose this burden on the Government at the

pleading stage, especially because "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." FED. R. CIV. P. 9(b); *Bollinger Shipyards*, 775 F.3d at 260 ("Knowledge need not be pled with particularity under Rule 9(b); it need only be pled plausibly pursuant to Rule 8.").

The Court concludes that the factual allegations as to scienter in the complaint are more than sufficient under Rule 8.

C. Materiality

For a false claim to violate the FCA, it must be material. *Escobar*, 579 U.S. at 191. The FCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). In the Fifth Circuit, the FCA requires "proof only that the defendant's false statements could have influenced the government's pay decision or had the potential to influence the government's decision, not that the false statements actually did so." *United States ex rel. Harman v. Trinity Indus. Inc.*, 872 F.3d 645, 661 (5th Cir. 2017). "[T]he False Claims Act is not a means of imposing treble damages and other penalties for insignificant regulatory or contractual violations." *Escobar*, 579 U.S. at 196.

Under *Escobar*, "a matter is material" if: (1) a reasonable person would attach importance to it in determining a "choice of action," or (2) "the defendant knew or had reason to know that the recipient of the representation attaches importance to the specific matter in determining his choice of action," whether or not a reasonable person would do so. *Id.* at 192 (internal quotation marks and citation omitted). *Escobar* identified several factors that are relevant to, but not automatically dispositive of, the materiality inquiry: whether the government has designated "compliance with a particular . . . requirement as a condition of payment," *id.* at 194; whether the violation of that requirement goes to the "essence of the bargain," *id*. at 193 n.5 (internal quotation

marks omitted); whether the violation is "minor or insubstantial," *id*. at 194; and whether the government has taken action when it had actual knowledge of similar violations, *id*. at 195. "[P]roof of materiality can include, but is not necessarily limited to, evidence that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the . . . requirement" at issue. *Id*. at 194–95.

Determining whether a violation is minor or insubstantial also appears to be a matter of common sense. In *Escobar*, the Supreme Court clarified that a condition can be material even where the Government does not expressly identify it as a condition of payment. *Id.* at 191 (noting that, even "if the Government failed to specify that the guns it orders must actually shoot . . . a reasonable person would understand the imperative of a functioning firearm"). On the other hand, even an express condition may be immaterial. For example, "[i]f the Government contracts for health services and adds a requirement that contractors buy American-made staplers, anyone who submits a claim for those services but fails to disclose its use of foreign staplers violates the False Claims Act." *Id.* at 195. If the Government regularly pays the service provider's claims, even knowing that foreign-made staplers were used, that is "strong evidence" that the condition that the contractor must use American-made staplers is not material. *Id.*

PCCA asserts that, "[u]nder the Supreme Court's ruling in *Escobar*, the government's decision to continue reimbursing compounding claims despite knowledge of the conduct it now claims was fraudulent requires dismissal." ECF No. 84 at 31 (citing *Escobar*, 579 U.S. at 195). The Court disagrees, for a number of reasons.

First, this argument is simply premature. For its proposition that, in light of *Escobar*, "courts routinely dismiss claims when the government knows of the violation of certain requirements and continues to pay claims," PCCA relies exclusively on out-of-circuit cases

applying, with one exception, the summary judgment standard, i.e., *after* an opportunity for discovery. *See* ECF No. 84 at 34–35.[9] The dearth of 12(b)(6) dismissals based on materiality is unsurprising given the holistic nature of the inquiry. *United States ex rel. Prather v. Brookdale Senior Living Cmtys., Inc.*, 892 F.3d 822, 831 (6th Cir. 2018) (explaining that the materiality inquiry is "holistic" in nature involving multiple, fact-intensive factors); *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 906–07 (9th Cir. 2017) (same); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 109–12 (1st Cir. 2016) ("*Escobar II*") (same). Indeed, the assessment of a false statement's ability to affect the government's payment decisions is often a matter for the jury. *See, e.g.*, *United States v. Hodge*, 933 F.3d 468, 474 (5th Cir. 2019) (affirming denial of motion for judgment as a matter of law on materiality); *United States ex. rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, No. SA-17-CV-00317-XR, 2023 WL 139319, at *10 (W.D. Tex. Jan. 9, 2023) (denying defendant's motion to reverse jury's materiality finding); *see also* Restatement (Second) of Torts § 538 cmt. e (1977) (recognizing that the materiality of a misrepresentation often depends on the jury's assessment of what is reasonable).

[9] Citing *United States ex rel. Berg v. Honeywell Int'l, Inc.*, 740 F. App'x 535 (9th Cir. 2018) (affirming *summary judgment* in favor of defendant); *United States ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017) (affirming *summary judgment in* favor of defendant); *United States ex rel. Hartpence v. Kinetic Concepts, Inc.*, Case No. 2:08-cv-01885-CAS-AGR, 2019 WL 3291582 (C.D. Cal. June 14, 2019) (granting *summary judgment* in favor of defendant—a decision later reversed by the Ninth Circuit based on, *inter alia*, its defective materiality analysis) *rev'd and remanded*, 44 F.4th 838 (9th Cir. 2022)).

PCCA does cite a single case dismissing an FCA claim for failing to adequately plead materiality. *See* ECF No. 84 at 35 (citing *United States ex rel. Kolchinsky v. Moody's Corp.*, 238 F. Supp. 3d 550 (S.D.N.Y. 2017). *Kolchinsky*, decided less than a year after *Escobar*, appears to rest on an understanding of *Escobar*'s holding that many courts, including the Fifth Circuit, have since rejected—that the government-action factor is dispositive. Compare *id.* at 558 ("materiality is absent at the pleading stage when the relator's chronology suggests that the Government knew of the alleged fraud, yet paid the contractor anyway.") with *United States ex rel. Lemon v. Nurses To Go, Inc.*, 924 F.3d 155, 161 (5th Cir. 2019) ("No one factor is dispositive, and our inquiry is holistic.") and *Montcrieff*, 2023 WL 139319, at *10 ("*Escobar* confirms that no one factor is dispositive of the fact-intensive materiality inquiry.").

Second, as a practical matter, AWP is inherently material under the language of the statute because, as part of the pricing calculation, it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4); s*ee also United States ex rel. Ven-A-Care v. Actavis Mid Atl. LLC*, 659 F. Supp. 2d 262, 271 (D. Mass. 2009) ("Reporting false AWPs had a natural tendency to influence the Government's actions, by inflating the amount of the Government's payment." (quotations and alteration marks omitted)); *Mylan Labs.*, 357 F. Supp. 2d at 321 ("Reporting false [wholesale acquisition costs] had a natural tendency to influence the [state's] actions, by inflating the amounts used to compute [estimated acquisition cost], and thus potentially the amount of the [state's] payment.").

Third, the complaint contains a number of allegations indicating that the inflated AWPs were material under both methods of proof set forth in *Escobar*—establishing that a "reasonable person" would attach importance to AWP inflation and that PCCA knew or had reason to know that the Government actually attached importance to it in making payment decisions.

The Government correctly observes as a matter of common sense that "a reasonable person would attach importance to the price paid in a transaction, particularly where, as here, the price is inflated." ECF No. 91 at 48 (citing *United States ex rel. Campbell v. KIC Dev., LLC*, No. EP-18-CV-193-KC, 2019 WL 6884485, at *12 (W.D. Tex. Dec. 10, 2019) ("Because 'a reasonable person would attach importance to' the price of a contract that he or she enters, the Government has adequately alleged materiality.")); *see also Escobar*, 579 U.S. at 192; Restatement (Second) of Torts § 538 cmt. e (recognizing that the materiality of a misrepresentation often depends on what is reasonable).

Indeed, the complaint suggests that PCCA itself endorsed this common-sense understanding: PCCA was concerned that disclosure of its selling prices in comparison to its

AWPs could lead payers to stop paying for compound claims. ECF No. 66 ¶ 154. In response to a customer request to include the selling price on its invoices, PCCA's Chief Operations Officer explained that it "would not be a very good idea" because it would allow insurance companies "to see both the AWP and the cost in one location." *Id.* ¶ 155. In seminars in 2013 and 2014, PCCA allegedly implored its members to never divulge its actual prices to auditors. *Id.* ¶ 156 ("Please, do not ever give them your costs." "You need to call us." "Do not give them your costs, ever." "It's going to create huge problems for you." "Don't let [auditors] see your acquisition costs. That is a disaster waiting to happen."). Instead, PCCA urged customers to report auditor requests for invoices to PCCA, which would then generate a report for the auditor excluding the actual selling price of PCCA's ingredients. *Id.* ¶ 157.

Regardless of whether a reasonable person would attach importance to the inflated AWPs, the complaint adequately alleges that PCCA knew or should have known between 2012 and 2015 that the Government considered AWP manipulation material to its payment decisions. The OIG Guidance explicitly warned that AWP manipulation combined with active marketing of the spread was "strong evidence" of an AKS violation.[10] 68 Fed. Reg. 23731, 23737 (May 5, 2003). AKS violations, in turn, are "inherently material" to the government's payment decision. *Marlin Med. Sols.*, 2022 WL 190308, at *8.

Ironically, PCCA argues that this guidance undermines the Government's position on materiality. *See, e.g.*, ECF No. 84 at 25 ("The government concedes in its Complaint that it was aware by at least 2003 that AWPs were often 'manipulat[ed.]'"). Just the opposite is true. The Government accurately observes that the 2003 OIG Guidance "put PCCA on notice that its actions

[10] Despite PCCA's assertion to the contrary, ECF No. 84 at 53 n.15, the OIG Guidance is not limited to Medicare and Medicaid, but rather applies to all "Federal health care programs" including TRICARE and also applies to "manufacturers of other products that may be reimbursed by federal health care programs." 68 Fed. Reg. at 23742 nn.1, 5.

were illegal. It did not put the government on notice of PCCA's illegal actions, which occurred between 2012 and 2015." ECF No. 91 at 55.[11] The government-action factor turns on whether the government paid a specific claim notwithstanding its *contemporaneous and actual* knowledge that the claim was false. *Montcrieff*, 2023 WL 139319, at *9. Actual knowledge of violations is not the same as awareness of allegations of violations. *See Escobar II*, 842 F.3d at 112; *United States ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F. Supp. 3d 734, 766 (W.D. Tex. 2020) ("It is not enough that the agency is aware of allegations of fraud, it must be aware of the fraud itself."). That the Government was aware of the possibility of AWP manipulation in general in 2003 is not evidence that it was actually aware of PCCA's false AWP-reporting when it paid pharmacies' claims for compound drugs between 2012 and 2015.

Similarly, PCCA argues that the Government's choice to renew its contract with ESI after ESI was itself accused of profiting off of fraudulently inflated AWPs is evidence that AWP inflation is immaterial. ECF No. 84 at 12 (referring to *United States v. Express Scripts, Inc.*, 602 F. App'x 880, 881 (3d Cir. 2015)). It is "notable," PCCA insists, that the Third Circuit found that news media coverage of potential illicit profits from inflated AWPs was sufficient to dismiss an FCA case against ESI under the public disclosure bar. *Id.* at 38. But the public disclosure bar has nothing to do with materiality; it bars relators from bringing claims based on publicly available information unless they were the original source of the information. 31 U.S.C. § 3730(e)(4)(A). Because the purpose of the public disclosure bar is to discourage relator freeriding, it does not

[11] Inexplicably, PCCA insists that the Court should disregard the 2003 OIG Guidance entirely in favor of a single footnote from the 2002 GAO Report, which, in describing AWP as a "list price," "sticker price," or "suggested retail price," notes that "the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers." ECF No. 84 at 26 (quoting GAO 02-969T). Of course, the descriptive reality that manufacturers can set any price does not necessarily imply that the prices they set are legal. Even if the footnote was intended to grant manufacturers permission to inflate AWPs with abandon, that permission was clearly retracted by the 2003 OIG Guidance explicit warning that AWP manipulation is illegal.

apply to the Government. *Express Scripts*, 602 F. App'x at 882–83.[12] The Government may assert a claim under the FCA no matter how many times the allegations against the defendant have appeared in the news.[13]

Moreover, TRICARE "signaled [a] change in position" in 2014 and 2015 based on the allegations in the relator's complaint and the GAO investigation, which weighs in favor of materiality. *See United States v. Luce*, 873 F.3d 999, 1009 (7th Cir. 2017) (finding materiality as a matter of law where government debarred defendant for noncompliance); *United States ex rel. Bibby v. Mortgage Inv'rs Corp.*, 987 F.3d 1340, 1347 (11th Cir. 2021) (finding fact issue where government knew of noncompliance and took actions); *United States ex rel. Mitchell v. CIT Bank, N.A.*, No. 4:14-CV-00833, 2022 WL 812364, at *13 (E.D. Tex. Mar. 16, 2022) (same where

[12] PCCA further asserts that it is "notable that the Department of Justice, which is not subject to the public disclosure bar, chose not to intervene in the case." ECF No. 84 at 38. This inference is so far removed from FCA caselaw and the 12(b)(6) standard that it verges on bad faith. A qui tam investigation focuses on whether the DOJ and its agency clients should (1) commit their limited resources to intervening in the qui tam case, (2) decline intervention and allow relators to move forward with the case alone, or (3) decline intervention and exercise their discretion to dismiss the relators' case. Given the diverse—and ultimately opaque—factors bearing on the Government's intervention decision, courts routinely exclude it from the materiality analysis altogether:

> In *Escobar* itself, the government chose not to intervene, and the Supreme Court did not mention this as a relevant factor in its materiality analysis. On remand, the First Circuit held that the relators had sufficiently pleaded materiality, without reference to the government's declination of intervention. Furthermore, the False Claims Act is designed to allow relators to proceed with a *qui tam* action even after the United States has declined to intervene. If relators' ability to plead sufficiently the element of materiality were stymied by the government's choice not to intervene, this would undermine the purposes of the [FCA].

Prather, 892 F.3d at 836 (citations omitted). In other words, the Government's decision not to intervene in *this* case would have limited probative value as to materiality at best. Here, PCCA suggests that the DOJ's decision not to intervene in a different lawsuit—against a different defendant involving different allegations—is more probative of materiality than the DOJ's actual choice to litigate this case. Such an inference against the Government is entirely unwarranted, especially at this stage of the proceedings.

[13] More generally, PCCA appears to confuse the Government's awareness that fraud exists within the compounding industry with actual and contemporaneous knowledge of PCCA's fraudulent conduct. This position is untenable, both practically and legally. To suggest that the Government's general awareness of fraud in a given industry excuses every one of its bad actors so long as the Government keeps paying claims in that industry—even as the Government takes active steps to investigate, prosecute, and prevent individual instances of fraud—would render the FCA utterly toothless. By this measure, the Government would be required to stop all payments to every stakeholder in the relevant industry at the first whiff of fraud in order to establish materiality.

government refused to pay claims when it had knowledge of similar violations). In November 2014, mere months after the relator filed his original complaint in this action, the DOD P&T Committee recommended a prior authorization process for compound claims, which was ultimately implemented in May 2015. *Id.* ¶¶ 160–61.

Finally, even the Government's continued payments in light of its *actual* awareness of misconduct is not proof per se that the misconduct is immaterial under the FCA. Courts have long held that an FCA defendant is "not automatically exonerated by any overlapping knowledge by government officials." *United States ex rel. Kreindler v. United Tech. Corp.*, 985 F.2d 1148, 1156 (2d Cir. 1993). There are many good reasons, including important public health and safety considerations, why the Government might continue to pay claims in such circumstances. *See United States ex rel. Harrison v. Westinghouse Savannah River Co.*, 352 F.3d 908, 917 (4th Cir. 2003) (government might have good reason to pay because the contract is "advantageous to the government" or is too far along to terminate). The Government must ensure the delivery of health care to many millions of Americans enrolled in its health insurance programs; "[it] does not enjoy the luxury of refusing to reimburse health care claims the moment it suspects there may be wrongdoing." *United States v. Berkeley HeartLab, Inc.*, No. 14-cv-230, 2017 WL 4803911, at *7 (D.S.C. Oct. 23, 2017).

PCCA nonetheless insists that, to establish materiality in this case, the Government should have denied claims for pain, scar, and *wound* creams on behalf of TRICARE beneficiaries—active and retired military personnel and their dependents. ECF No. 84 at 30–42. The Court declines to endorse a theory of materiality that would, at a minimum, force the Government to deny care to people who have made sacrifices for their country, and, at worst, create a national security risk.[14]

[14] The complaint does in fact allege that TRICARE denied payment "directly in response to the exorbitant reimbursements." ECF No. 66 ¶ 171. This allegation contradicts PCCA's contention that the complaint "fails to allege

In short, the Court concludes that the Government has plausibly alleged that the inflated AWPs were material to TRICARE's reimbursement of PCCA members' claims for compound drugs containing PCCA's ingredients.

D. Causation

The FCA reaches anyone who "knowingly assist[s] in causing" the Government to pay claims grounded in fraud, "without regard to whether that person ha[s] direct contractual relations with the government." *Riley*, 355 F.3d at 378 (quotations omitted). "Causation under the FCA requires proximate cause, not merely 'but for' cause." *United States ex rel. Morsell v. Symantec Corp.*, 471 F. Supp. 3d 257, 308 (D.D.C. 2020); *see also U.S. ex rel. Cimino v. Int'l Bus. Mach. Corp.*, 3 F.4th 412, 420 (D.C. Cir. 2021). Proximate cause is a common-law concept focused on the scope of risk and foreseeability. *See Paroline v. United States*, 572 U.S. 434, 445 (2014). The Supreme Court has labeled proximate cause as "a flexible concept." *Id.* at 444 (quoting *Bridge v. Phoenix Bond & Indem. Co.*, 553 U.S. 639, 654 (2008)). It "is often explicated in terms of foreseeability or the scope of the risk created by the predicate conduct" and "thus serves, *inter alia*, to preclude liability in situations where the causal link between conduct and result is so attenuated that the consequence is more aptly described as mere fortuity." *Id.* at 445.

"A defendant's conduct may be found to have caused the submission of a claim for . . . reimbursement if the conduct was (1) a substantial factor in inducing providers to submit claims

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facts sufficient to allow the Court to conclude . . . TRICARE ever denied a single claim for payment based on the AWP of a compounded medication containing bulk substances." ECF No. 84 at 30. PCCA's reference to the payment in September 2017 of a single claim submitted in April 2015, *id.*, does not negate the fact that following newly implemented controls, TRICARE "refuse[d] to pay claims in the mine run of cases." *Escobar*, 579 U.S. at 195.

Similarly, PCCA reads too much into the 2014 GAO report's description of the DOD's temporary reversal of its June 2013 decision to stop reimbursing claims for compound drugs based on "beneficiary complaints and enactment of new legislation concerning compounded drug safety and quality[.]" ECF No. 84-1 at 8–9. The DOD's choice to temporarily postpone the change while awaiting new legislation does not suggest that the Government considered AWP inflation to be minor or insubstantial.

for reimbursement, and (2) if the submission of claims for reimbursement was reasonably foreseeable or anticipated as a natural consequence of defendants' conduct." *United States ex rel. Ruckh v. Salus Rehab.*, 963 F.3d 1089, 1107 (11th Cir. 2020) (quotations omitted).

The complaint plausibly alleges that PCCA's actions were (1) a substantial factor in causing customers to submit inflated claims to TRICARE; and (2) the submission of claims to TRICARE was reasonably foreseeable or anticipated as the natural consequence of PCCA's actions. *See* ECF No. 66 ¶¶ 150–51. The complaint provides extensive detail about PCCA's fraudulent AWP scheme (*id*. ¶¶ 52–64) and use of high AWPs and AWP spreads to drive sales of its ingredients (*id*. ¶¶ 73–111). The complaint also describes PCCA's efforts to assist its customers in maximizing profitability from its AWPs through training, billing software, consulting services, and educational seminars on third-party billing and "custom pricing strategies." *See id.* ¶¶ 112–17. PCCA's efforts allegedly fueled a rapid increase in the submission of compound prescription claims to TRICARE containing PCCA ingredients with inflated AWPs. *See id.* ¶¶ 133–34, 139–40. Accordingly, the Court concludes that the Government has plausibly alleged that its losses were proximately caused by PCCA's unlawful conduct. *See United States v. Hodge*, 933 F.3d 468, 475 (5th Cir. 2019), *as revised* (Aug. 9, 2019) (citing expert testimony about deficiently underwritten loans that resulted in claims).

II. Common Law Claims

The Government's common law claims for payment by mistake, fraud, and unjust enrichment are governed by federal common law, not Texas common law. "The authority of the United States in relation to funds disbursed and the rights acquired by it in relation to those funds are not dependent upon state law." *United States v. Vernon Home Health, Inc.*, 21 F.3d 693, 695 (5th Cir. 1994) (citing *United States v. Kimbell Foods*, 440 U.S. 715, 726 (1979)); *see also Bynum*

v. FMC Corp., 770 F.2d 556, 568 (5th Cir. 1985) (holding that federal common law governs the analysis of claims where the "outcome will have an immediate effect on the federal treasury").

PCCA asserts that the Government's common law claims must fail because the Complaint does not explicitly plead these claims in the alternative. ECF No. 84 at 65. This argument is meritless. "No technical form is required" in pleadings. FED. R. CIV. P. 8(d)(1). A "party may state as many separate claims or defenses as it has, regardless of consistency," and "[p]leadings must be construed so as to do justice." FED. R. CIV. P. 8(d)(3), (e); *see United States v. BNP Paribas SA*, 884 F. Supp. 2d 589, 616 (S.D. Tex. 2012) ("[S]ince parties may plead alternative and inconsistent theories of recovery, a motion to dismiss is not the appropriate vehicle for determining whether the guarantees preclude claims for unjust enrichment and/or payment by mistake."); *Campbell*, 2019 WL 6884485, at *17–18 (collecting cases in which courts have allowed claims under federal common law, including claims for payment by mistake and unjust enrichment, to proceed concurrently with FCA claims as an alternative theory of relief). Accordingly, the Court will address the substance of the Government's allegations in support of its claims under federal common law.

A. Payment by Mistake

"The Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid." *United States v. Wurts*, 303 U.S. 414, 415 (1938). "No statute is necessary to authorize the United States to sue in such a case[; t]he right to sue is independent of statute." *Id.* "In a false claim payment dispute, the government is entitled to reimbursement for payments . . . where it is shown: (1) payments were made (2) under the belief that they were properly owed; (3) that belief being erroneously formed; and (4) the mistaken belief was material to the decision to pay." *United States v. Medica Rents Co.*, 285 F. Supp. 2d 742, 776

(N.D. Tex. 2003), *aff'd* 2008 WL 3876307 (5th Cir. Aug. 19, 2008) (citing *United States ex rel. Trim v. McKean*, 31 F. Supp. 2d 1308, 1316 (W.D. Okla. 1998)). The Government "is entitled to obtain repayment from a third party into whose hands the mistaken payments flowed where that party participated in and benefitted from the tainted transactions." *LTV Educ. Sys., Inc. v. Bell*, 862 F.2d 1168, 1175 (5th Cir. 1989). "The order in which the funds flowed is immaterial," *id.*, as is the defendant's awareness that the payment was mistaken. *Medica Rents*, 285 F. Supp. 2d at 776 (citing *United States v. Mead*, 426 F.2d 118, 125 n.6 (9th Cir. 1970)).

PCCA contends that the Government's claim fails because TRICARE proceeds were paid to PCCA's member pharmacies and did not flow to PCCA directly.[15] ECF No. 84 at 66. Here, PCCA relies on the district court's decision *Caremark* for the proposition that "plaintiff cannot establish payment by mistake where the plaintiff did not make payments directly *to* the defendant" *Id.* (emphasis added) (citing *United States ex rel. Ramadoss v. Caremark Inc.*, et al., No. SA-99-CA-00914-WRF, 2008 WL 3978101 (W.D. Tex. 2008)). The *Caremark* court expressly rejected the government's argument that indirect benefit in increased revenues from its non-government customers was sufficient to make out a payment-by-mistake claim. *Id.* In *Caremark*, the court granted summary judgment on Texas' payment-by-mistake claim, reasoning that Caremark did not receive "payments made by Texas Medicaid—either directly *or indirectly*" and there was no evidence that Caremark benefitted from the alleged overpayments. 2008 WL 3978101, at *11 (emphasis added).

Here, the Government has alleged that PCCA both caused and indirectly benefitted from payments to TRICARE by reporting fraudulently inflated AWPs and marketing the resulting

[15] PCCA also suggests that a payment by mistake claim requires a contractual relationship. *See* ECF No. 84 at 67 n.18. The opposite is true. *See Campbell*, 2019 WL 6884485, at *17 ("So-called quasi-contract theories such as payment by mistake . . . are generally precluded by the existence of an express contract.").

spreads to drive sales of its ingredients. ECF No. 66 ¶¶ 158–63, 193–96. Specifically, the Government alleges that PCCA benefitted from TRICARE's reimbursement through explosive growth in PCCA's sales to its customers, profits, and dividends. *Id.* ¶¶ 158–63.

B. Unjust Enrichment

Unjust enrichment "allows a plaintiff to recover money dictated by the needs of justice and fairness." *See Campbell*, 2019 WL 6884485, at *17 (quotations omitted). Unjust enrichment applies when the defendant "is in possession of funds which in good conscience and justice should not be retained, but should be delivered to the rightful owner." *Medica-Rents*, 285 F. Supp. 2d at 777. "[R]ecovery under unjust enrichment is justified when one person obtains a benefit from another by fraud, duress, or the taking of an undue advantage." *United States v. Medica-Rents Co.*, Nos. 03-11297, 06-10393, 07-10414, 2008 WL 3876307, at *3 (5th Cir. Aug. 19, 2008).

As with the claim for payment by mistake, PCCA contends the Government's unjust enrichment claim must be dismissed because any benefit was conferred upon the member pharmacies in the form of allegedly excessive reimbursement of compounded medications rather than upon PCCA itself. ECF No. 84 at 67–68. PCCA insists that the only "benefit" it received was from the member pharmacies through "membership fees" and revenue from purchases of ingredients, neither of which properly belonged to the United States. *Id.* The Government responds that, by its fraudulent conduct, PCCA substantially increased its sales, profits, and dividends, and was unjustly enriched at the Government's expense. ECF No. 91 at 72 (citing ECF No. 66 ¶¶ 158–63, 193–96). Indeed, according to the complaint, once TRICARE implemented additional controls for compound claims, PCCA's sales decreased sharply. ECF No. 66 ¶¶ 161–62. PCCA's argument as to the "benefits" it incurred merely speaks to the proper measure of restitution.

As alleged, the Government asserts that equity, good conscience, justice, and fairness require that PCCA return any ill-gotten gains to the Government. *Id.* ¶¶ 193–96. The Court can plausibly infer from the allegations in the complaint that PCCA benefitted from its alleged fraudulent inflation of AWPs and violation of the AKS. *Capshaw*, 2018 WL 6523322, at *2. Accordingly, the Government has adequately pled a claim for unjust enrichment.

C. Common Law Fraud

To plead common law fraud, "the Government must plausibly show there was (1) a false representation (2) in reference to a material fact (3) made with knowledge of its falsity (4) and with the intent to deceive (5) with action taken in reliance upon the representation." *United States ex rel. Capshaw v. White*, No. 3:12-CV-4457-N, 2018 WL 6523322, at *2 (N.D. Tex. Dec. 11, 2018) (quotations omitted) (citing *Pence v. United States*, 316 U.S. 332, 338 (1942)). A fraud claim is similar to a claim under FCA but includes "the elements of reliance and damages." *See Grubbs*, 565 F.3d at 189. Fraud carries a more demanding pleading standard than the FCA because to plead the elements of reliance and damages, a plaintiff has to "offer particular and reliable indicia that false bills were actually submitted as a result of the scheme—such as dates that services were fraudulently provided or recorded[.]" *Id.; see, e.g.*, *Capshaw*, 2018 WL 6523322, at *2 (complaint satisfied the pleading requirements set forth in *Grubbs* by "detailing at least twenty-four (24) specific examples of patient referrals that resulted in the submission of at least 180 Medicare claims" resulting in over $18 million of Medicare payments based on allegedly illegal referrals).

PCCA contends that the Government's fraud claims fails on the very first element because the complaint does not and cannot allege that PCCA made any representation whatsoever *to* TRICARE given that PCCA reported AWPs to third-party publishers, not to the Government. ECF

No. 84 at 70 (citing *Nat'l Rifle Assoc. of Am. v. Ackerman Mcqueen, Inc.*, No. 3:19-CV-2074-G, 2021 WL 3618113, at *16 (N.D. Tex. Aug. 16, 2021) ("That the fraudulent statement must be made to the plaintiff is baked into the elements of fraud.")). As the Government points out, however, the law does not focus on whether an alleged misrepresentation was directly transmitted to the plaintiff; rather, it focuses on whether the defendant had reason to expect the misrepresentation would reach the plaintiff and induce reliance. *See OurLink, LLC v. Goldberg*, No. 3:08-CV-0745-P, 2008 WL 11425698, at *2–3 (N.D. Tex. Dec. 3, 2008) (rejecting defendants' argument that misrepresentations were not made to the plaintiff because the "[c]omplaint clearly alleges that the [defendants] had reason to expect that [plaintiff] would rely on the alleged misrepresentations").

PCCA further objects that the Government cannot state a claim for fraud because TRICARE was aware of the fraud or at least "circumstances were sufficient" to put it on notice that the AWPs did not correspond to the average price of the ingredients, and thus TRICARE's reliance on the AWPs was not justified. ECF No. 84 at 69. Unless a representation is "obviously false," the recipient of a fraudulent misrepresentation of fact is justified in relying on its truth, even when he might have discovered the falsity of the representation had he made an investigation. *See In re Mercer*, 246 F.3d 391, 417 (5th Cir. 2001) (citing Restatement (Second) of Torts §§ 540–41 (1977)). "[R]easonable reliance is often a question of fact for the jury rather than a question of law for the court" because the word 'reasonable' (or sometimes 'justifiable') is inherently imprecise, . . . involving many factors to consider and balance, no single one of which is dispositive." *STMicroelectronics, N.V. v. Credit Suisse Sec. (USA) LLC*, 648 F.3d 68, 81 (2d Cir. 2011) (alteration marks and quotations omitted) (citing *Brown v. E.F. Hutton Grp., Inc.*, 991 F.2d 1020, 1032 (2d Cir. 1993) (collecting cases addressing reasonable-reliance factors in the context of

securities fraud, including: the relative sophistication of the parties, the existence of longstanding business relationships, access to the relevant information, concealment of the fraud, and the opportunity to detect the fraud).

Here, the Government has alleged that PCCA actively concealed the selling price of its ingredients, intentionally inflated its AWPs to meet or exceed those of its competitors, and gave customers a way to manipulate their U&C pricing to ensure that TRICARE relied on AWPs in reimbursing claims for compounds containing PCCA ingredients. ECF No. 66 ¶¶ 69, 70, 72, 117, 153–57. Given the opacity of the market for compounding ingredients and the fact the PCCA's competitors and customers were submitting similar figures in their respective AWPs and U&C pricing, it is not clear to the Court that PCCA's AWPs were so obviously false that the Government should have known that they were false without conducting any investigation. Taken as true, these facts are sufficient to plausibly allege that TRICARE's reliance on PCCA's AWPs was justified, even under Rule 9(b)'s heightened pleading standard.

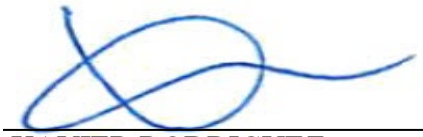
The complaint alleges that PCCA knowingly made material misrepresentations in reporting inflated AWPs, which TRICARE relied on in determining reimbursement, and that, if PCCA had not inflated its AWPs, TRICARE would not have reimbursed its ingredients at the inflated amounts. *Id.* ¶ 199. The Government alleges that TRICARE paid hundreds of millions of dollars in excess reimbursement for tens of thousands of false and fraudulent compound prescription claims containing PCCA ingredients, and provides 325 alleged examples of claims. *See id.* ¶ 179; ECF No. 66-22. This is sufficient at the pleading stage. *Capshaw*, 2018 WL 6523322, at *2.

CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss (ECF No. 84) is **DENIED**.

It is so **ORDERED**.

SIGNED this 27th day of March, 2023.



XAVIER RODRIGUEZ
UNITED STATES DISTRICT JUDGE